

Congress of the United States
Washington, DC 20515

February 22, 2022

Dr. Robert M. Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We respectfully urge the Food and Drug Administration (FDA) to end the blanket three-month blood donation deferral period for men who have sex with men (MSM) and transition to an individual risk assessment to determine donor eligibility. The current policy is overly stringent given the scientific evidence, advanced testing methods, and safety and quality control measures within FDA-qualified blood donation centers; stigmatizes members of the LGBTQI+ community; and needlessly restricts the blood supply while our nation combats a critical blood shortage and the COVID-19 pandemic.

On January 11, 2022, the American Red Cross declared the first-ever national blood crisis amid the “worst blood shortage in over a decade.”¹ The COVID-19 pandemic and harsh winter weather have cut the number of blood drives and the number of people donating blood, resulting in some hospitals receiving less than a quarter of the blood requested.¹ At a time when blood supply shortages are forcing hospitals to cancel surgeries and change treatment plans, the FDA’s policy puts patients at risk.²

The existence of any deferral period tied to MSM further stigmatizes HIV/AIDS as a “gay disease” and members of the LGBTQI+ community as “unclean.” Sexual contact between two men is not listed as a risk factor for HIV/AIDS by the Centers for Disease Control and Prevention or the World Health Organization, yet the FDA directs any male donors with a “history in the past three months of sex with another man” to defer donation for three months.³ This policy uses sexual contact between two men as a proxy for unsafe sex that is likely to contaminate the blood supply. This inaccurate association contributes to homophobia, not a safe blood supply.

¹ <https://www.redcross.org/about-us/news-and-events/press-release/2022/blood-donors-needed-now-as-omicron-intensifies.html>

² https://americasblood.org/wp-content/uploads/2022/01/Joint-Statement-on-Blood-Supply_Jan-2022.pdf

³ <https://www.cdc.gov/hiv/basics/hiv-transmission/increase-hiv-risk.html>, <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>, and <https://www.fda.gov/media/92490/download>

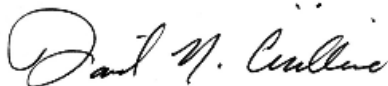
The medical community in the United States agrees that an individual risk assessment for all donors is the best way to protect our nation's blood supply. In fact, the American Medical Association supports "removing categorical restrictions for blood donations by MSM," and basing donation eligibility on "a person's individual risk."⁴ The FDA has made clear it will not consider these changes until the Assessing Donor Variability And New Concepts in Eligibility (ADVANCE) Study is completed. However, the results of the study have been delayed until mid-2022 due to difficulties recruiting participants and the COVID-19 pandemic.⁵ What is the FDA doing to expedite recruitment and help meet the goal of 2,000 participants for the study?

At least 17 countries, including Spain, have no restrictions on MSM blood donation.⁶ Additionally, in June 2021, the United Kingdom ended its three-month blood donation deferral period for MSM and implemented a donation eligibility policy based on individual risk.⁷ These nations prove that an individual risk assessment that does not stigmatize members of the LGBTQI+ community is sufficient to screen blood donors and protect our nation's blood supply.

After celebrating National Blood Donor Month in January, we urge you to live up to your commitment to ensure blood donation policies are "based on science, not fiction or stigma."⁸ We urge the FDA to end the three-month blood donation deferral period for MSM and implement an individual risk assessment policy for blood donation.

We thank you in advance for your timely consideration of this matter and look forward to your response.

Sincerely,



David N. Cicilline
Member of Congress



Barbara Lee
Member of Congress

⁴ <https://www.ama-assn.org/press-center/press-releases/ama-statement-new-fda-guidelines-msm-blood-donation#:~:text=Apr%20%2C%202020&text=%22The%20FDA%20took%20a%20step,prohibited%20MSM%20from%20donating%20blood>

⁵ <https://advancestudy.org/>

⁶ <https://www.reuters.com/article/us-global-lgbt-health-factbox-trfn/what-are-the-blood-donation-rules-globally-for-gay-and-bisexual-men-idUSKBN22N2GS>

⁷ <https://www.npr.org/2021/06/16/1007006637/gay-and-bisexual-men-are-now-allowed-to-donate-blood-in-england-scotland-and-wal>

⁸ <https://abcnews.go.com/Health/biden-administration-speaks-federal-blood-donation-policy-impacting/story?id=82328733>



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